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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,911	01/07/2002	Frank E. Manning	GUID.038US01	4087
7590 11/16/2004			EXAMINER	
Mark A. Hollingsworth CRAWFORD PLLC Suite 390 1270 Northland Drive Mendota Heights, MN 55120			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 11/16/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/041,911

Applicant(s)

MANNING ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 24-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 8, 15, 24 – 31, 37 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,638,268 to Niazi.

In regards to claims 1, 2, 8, 15, 24 – 31, 37 and 42, Niazi discloses applicant's claimed invention including an outer sheath (11) having an open lumen and a pre-shaped distal end (Col. 4, lines 4 – 31); an inner sheath (12) having an open lumen configured to receive a payload, the inner sheath disposed within the open lumen of the outer sheath, the inner sheath being axially rotatably and longitudinally translatable relative to the outer sheath (Col. 3, lines 12 – 15), a distal end of the inner sheath conforming to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assuming a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 3, lines 10 – 23; Col. 4, lines 4 – 8); a steering tendon along the outer sheath, a distal end of the tendon connected to a distal tip of the outer sheath (Col. 3, lines 55 – 61); a guide handle connected to a proximal end of the outer sheath; and a steering mechanism (29) pivotably connected to the handle, the steering mechanism connected to a proximal end of the tendon and providing a pulling force on the steering tendon to adjust a shape of the preshaped distal end of the outer sheath (Col. 3, line 61 – Col. 4, line 3). Niazi

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discloses an occlusion device (21) connected to the distal end of the outer sheath (Col. 3, lines 43 – 46). Niazi discloses the outer sheath having a second lumen, the steering tendon disposed within the second lumen of the outer sheath (Col. 3, lines 55 - 59). Niazi discloses the payload comprising a pacing lead configured for implantation with a coronary sinus or branch vessel (Col. 3, lines 29 – 31). Niazi discloses the payload comprising a guide wire and a lead having a lumen dimensioned to receive the guide wire (Col. 5, lines 57 – 64). The open lumen disclosed by Niazi is capable of receiving a payload comprising an injectable media (Col. 4, lines 56 – 58).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 4, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claims 1 and 24 above, and further in view of U.S. Patent No. 5,409,469 to Schaerf.

In regards to claims 3, 4, 32 and 33, Niazi fails to disclose a longitudinally disposed pre-stress line extending from the proximal end to the distal end of the outer or inner sheath. However, Schaerf discloses a lead introducer having a longitudinally disposed pre-stress line (63) extending from the proximal end to the distal end (Col. 5, lines 25 – 45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi to include pre-stress lines as taught by Schaerf to aid in the removal of the sheath without requiring the sheath to be removed from an end of the lead (Col. 5, lines 25 – 29).

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5. Claims 5, 6, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claims 1 and 24 above, and further in view of U.S. Patent Application Publication No. 2001/0039413 to Bowe.

6. In reference to claims 5, 6, 34 and 35, Niazi fails to disclose at least one electrode on the distal end of the inner or outer sheath, and an electrical conductor being coupled to the electrode and being disposed within the inner or outer sheath. However, Bowe discloses a guide catheter having at least one electrode on the distal end of the inner sheath and at least one electrical conductor coupled to the at least one electrode, the conductor being disposed within the inner sheath [0046]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi to include at least one electrode as taught by Bowe in order to provide energy to the tissue to treat different ailments of the heart. Furthermore, it would have been an obvious engineering design choice to place the electrode as disclosed by Bowe on the outer sheath in that the electrode would perform the same function being placed on the outer sheath as well as the inner sheath.

7. Claims 7, 9, 10, 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claims 1 and 24 above, and further in view of U.S. Patent No. 6,533,770 to Lepulu et al.

In reference to claims 7, 9, 10, 36, 38 and 39, Niazi discloses an occlusion device being connected to the pre-shaped distal end of the outer sheath (Col. 3, lines 43 – 46). However, Niazi fails to disclose an occlusion device being connected to the inner sheath and at least one pressure sensing device connected to the inner or outer sheath. However, Lepulu et al. discloses a guiding member having an occlusion device connected to the distal end of the inner sheath and a pressure sensing device located within the inner sheath (Col. 17, lines 26 – 35). It would have been obvious

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to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Niazi to include an occlusion device and a pressure sensing device as taught by Lepulu et al. in order to further the diagnostic capabilities of the device. Furthermore, placing the occlusion device and the pressure sensing device on the inner or outer sheath is a design consideration within the skill of the art.

8. Claims 11 – 14, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,638,268 to Niazi as applied to claims 1 and 24 above.

In regards to claims 11, 12 and 40, Niazi discloses the outer sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 180 degrees and a bend radius from about 1 cm to 7 cm. Niazi discloses the inner sheath having a substantially circular curve proximally adjacent to a strait section, the curve having a bend radius ranging from about 0 degrees to about 150 degrees and a bend radius from about 1 cm to 5 cm (Col. 4, lines 4 – 23). However, Niazi fails to disclose the tip of the outer sheath having a length of about 1 cm to 5 cm and the tip of the inner sheath having a length of about 0.5 cm to about 4.0 cm. Niazi teaches that the predetermined shape and size of the curve can be changed to accommodate different heart sizes (Col. 4, lines 25 – 31). It would have been obvious to modify the size and shape of the predetermined curves as needed to accommodate different heart sizes as taught by Niazi.

In reference to claims 13, 14 and 41, Niazi discloses the tendon being disposed along the outer sheath (Col. 3, lines 55 – 59), but fails to disclose the tendon being on outer surface of the sheath or within the open lumen of the sheath. However, due to the lack of criticality in the specification for the positioning of the steering tendon, it would have been obvious to one having

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ordinary skill in the art at the time the device was made to position the tendon on the surface or within the interior of the lumen as desired.

### *Response to Arguments*

9. Applicant's arguments filed 8/6/04 have been fully considered but they are not persuasive. Applicant has asserted that Niazi fails to disclose an inner sheath that has a distal end with a pre-formed shape, such that the inner sheath conforms to a shape of the outer sheath when retracted, but assumes the pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath. Applicant asserts that Niazi is wholly silent on a pre-formed shape of its inner catheter 12. However, the Examiner disagrees. Niazi discloses an inner sheath 12 that slides in and out of an outer sheath 11. The inner sheath is formed of a more pliable material than the outer sheath (Col. 3, lines 12 – 14). Niazi clearly states that both the inner and outer sheaths have a predetermined shape and stiffness to maintain shape during manipulation into the heart (Col. 4, lines 4 – 7). Thus, because both sheaths have a pre-formed shape and the inner sheath is formed of a more pliable material, the outer sheath controls the shape of the inner sheath while retracted into the outer sheath. However, because the inner sheath is disclosed as having a pre-formed shape, upon being extended beyond the distal end of the outer sheath, the inner sheath would take its pre-formed shape.

Additionally, Applicant has asserted that U.S. Patent Application Publication No. 2001/0039413 to Bowe and the instant application were, at the time the invention were made, owned by common assignee Cardiac Pacemakers, Inc, and, therefore, is not a qualified reference under 35 U.S.C. § 102(e) and is therefore not available under 35 U.S.C. § 103. However, the instant application was filed on 1/7/02 and U.S. Patent Application Publication No. 2001/0039413 to

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Bowe was published on 11/8/01. Therefore, U.S. Patent Application Publication No.

2001/0039413 qualifies as prior art under 35 U.S.C. § 102(a) as shown below:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as U.S. Patent Application Publication No. 2001/0039413 at the time this invention was made. Accordingly, U.S. Patent Application Publication No. 2001/0039413 is disqualified as prior art through 35 U.S.C. 102(e), (f) or (g) in any rejection under 35 U.S.C. 103(a) in this application. However, this applied art additionally qualifies as prior art under another subsection of 35 U.S.C. 102 and accordingly is not disqualified as prior art under 35 U.S.C. 103(a).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the inventor of this application, and is therefore, not the invention "by another", or by antedating the applied art under 37 CFR 1.131.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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